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EXAMINER	
FORD, ALLISON M	
ART UNIT	**PAPER NUMBER**
1651	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/763,004	POULIN, PAUL	
	Examiner	Art Unit	
	Allison M. Ford	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 July 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-40* is/are pending in the application.

4a) Of the above claim(s) *16-30* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-15 and 31-40* is/are rejected.

7)☒ Claim(s) *31 and 37* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *22 January 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of Group I, claims 1-15 and 31-40 in the reply filed on 21 July 2005 is acknowledged.

Status of Application

Claims 1-15 and 31-40 are being examined for patentability. Claims 1-40 remain pending in the current application, of which claims 16-30 have been withdrawn from consideration.

Claim Objections

Claim 31 is objected to because of the following informalities: it appears the word "a" is missing in the 9th line of the claim; the corrected line should read, "...together forms a kit for the long-term storage of hereditary..." Appropriate correction is required.

Claim 37 is objected to because of the following informalities: the word "four" should be written out in the second line of the claim.

Claim Rejections - 35 USC § 112

Claims 1-15 and 31-40 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for successful long-term storage of DNA by providing lyophilized DNA with amorphorous disaccharides, does not reasonably provide enablement for the successful long-term storage of DNA by providing lyophilized DNA with any sugar. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to successful make or use the invention commensurate in scope with these claims.

Applicant's specification provides no working examples of lyophilizing isolated genomic DNA in the presence of any sugars. However, it is known in the art that some sugars have the ability to protect DNA and proteins during lyophilization. For example, Volkin et al (US 2002/0156037) teach that amorphous sugars such as sucrose and lactose greatly stabilize DNA during lyophilization; however, crystalline sugars, such as mannitol do not enhance DNA stability compared to controls (See Volkin et al, Pg. 24, paragraph 0224). Additional support for amorphous disaccharides lactose, maltose, trehalose, and cellobiose protecting DNA from degradation during lyophilization is provided in Ando et al (J. Pharm. Sci, 1999) (See Ando et al, Pg. 128, col. 1-2). Therefore, while the art recognizes the cryoprotectant properties of amorphous disaccharides over DNA during lyophilization, there is not support, either in the art or in the present specification, for the use of any sugar as a protectant; in fact Volkin et al specifically teach away from using crystalline sugars, as their crystalline structure damages DNA during lyophilization. Therefore applicant's scope is limited to what they have shown, and what is taught in the art, which is limited to the use of amorphous disaccharides.

Claim 13 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for successful long-term storage of DNA by providing lyophilized DNA with sugar and EDTA, does not reasonably provide enablement for the successful long-term storage of DNA by providing lyophilized DNA with sugar and TRIS buffer. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to successful make or use the invention commensurate in scope with these claims.

Applicant's claim 13 is directed to a method for the long-term storage of hereditary information comprising providing a genetic sample comprising lyophilized DNA, sugar, and EDTA or Tris buffer, wherein the DNA is substantially free of magnesium and wherein the lyophilized DNA is stored in a hermetically sealed UV blocking container under and inert gas.

Applicant's specification provides no working examples of lyophilizing isolated genomic DNA samples comprising EDTA or Tris buffer. However, Ando et al (J. Pharm Sci, 1999) teach that EDTA effectively protects DNA from degradation during lyophilization; therefore applicants are enabled for inclusion of EDTA. However, Ando et al further teaches that Tris buffer increases DNA degradation, most likely due to the presence of sodium phosphate, present in the Tris buffer, which form crystals upon freezing (See Ando et al, Pg. 128, col. 1-2 and Table 3). Thus the art specifically teaches away from the use of Tris buffer in DNA lyophilization procedures. Therefore, while the art teaches that including amorphous sugars and EDTA in DNA solutions can decrease the degradation of DNA during lyophilization, thereby allowing successful long-term storage of DNA, inclusion of Tris buffer will negatively effect the DNA by degrading the DNA.

Claims 1-15 and 31-40 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

While applicants state that sucrose or trehalose are suitable disaccharide sugars that can be successfully utilized in the presently claimed methods, they fail to provide a sufficient description of a representative number of species which is required to claim the entire genus of sugars. Sugars comprise a complex group of chemicals that includes a variety of molecular shapes, and structures, including linear molecules (i.e. mannitol), monosaccharides (i.e. glucose), disaccharides (i.e. lactose), and polysaccharides (i.e. cellulose); as stated above, the art teaches away from the use of several types of sugars for DNA protection purposes, specifically mannitol (See Volkin et al, Pg. 24, paragraph 0224). Therefore, with no disclosure of relevant, identifying characteristics, such as structure or other physical or chemical properties, or functional characteristics specific to the enabled species of sugars (amorphorous

disaccharides), applicant's sole mention of sucrose and trehalose is not sufficient to show applicant was in possession of the claimed genus of all sugars at the time of the invention. *See Eli Lilly,* 119F. 3d. at 1568, 43 USPQ2d at 1406. See MPEP § 2163.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-15 and 31-40 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Applicant's claim 1 is directed to a method for long-term storage of hereditary information, comprising providing a genetic sample comprising lyophilized DNA and sugar in a hermetically sealed UV blocking container under an inert gas, wherein the DNA is substantially free of magnesium. Applicant's claim 31 further requires a step of placing the sealed UV blocking container into a holding member that is inserted into an aperture of a box that together forms a kit for the long-term storage of hereditary information.

Applicant's claim 1 is confusing because it is not clear how the step present in the body of the claim accomplishes the purpose outlined in the preamble. First, the preamble itself is confusing, as "long-term storage" does not appear to require any positive steps, rather *storage* infers no steps are required, the sample is merely left untouched. Rather it appears applicant is intending to claim a method for preparing a genetic sample for long-term storage, or applicant intends to claim the product produced. Second, even under the interpretation that the claim is to be directed to a method of preparing a genetic sample for long-term storage, the body of the claim does not outline any steps for such preparation. The body of the claim merely recites a single step of providing a prepared genetic sample, no steps or information are provided

on how to prepare this sample. Therefore, the body of claim 1 does not appear to be commensurate in scope with the preamble.

Similarly, claim 31 is confusing because the steps outlined in the claim do not appear to accomplish the purpose recited in the preamble. First, the preamble itself is confusing, as "long-term storage" does not appear to require any positive steps, rather *storage* infers no steps are required, the sample is merely left untouched. Second, the steps of the method do not appear to be directed to storing the sample, but rather to producing a kit for storage of hereditary material. Therefore, the body of claim 31 does not appear to be commensurate in scope with the preamble.

Additionally, both claims 1 and 31 require the DNA to be substantially free of magnesium; however, the term "substantially free" in claims 1 and 31 is a relative term which renders the claim indefinite. The term "substantially free" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Therefore one skilled in the art cannot determine the scope of the claim.

Applicant's claim 4 is directed to the method of claim e, wherein the disaccharide is trelose or sucrose. Trelose is unknown; it appears applicant intended for the disaccharide to be trehalose or sucrose.

Applicant's claim 6 is directed to the method of claim 1, wherein the UV blocking container comprises borosilicate. This is confusing, because borosilicate, by itself, is not a UV blocking material, but a UV-transparent material (See Warashina et al (US Patent 6,121,621, col. 3, ln 58-63)).

Applicant's claim 10 is directed to the method of claim 1 and further requires a step of lyophilizing the DNA. However, applicant's claim 1 requires providing lyophilized DNA; therefore it is not clear how or why lyophilized DNA would need to be further lyophilized.

Applicant's claim 11 is directed to the method of claim 1, wherein the DNA is obtained from the blood of a subject. It is not clear if applicant is intending to claim a further step in the method of claim 1,

wherein blood is obtained from a subject and prepared as the sample described in claim 1, or if applicant is merely trying to further define the product used in the method of claim 1, in such case the DNA would be considered a product-by-process. Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process. *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985).

Applicant's claim 15 is directed to the method of claim 1 and further requires a step of isolating DNA. It is not clear if applicant is intending to claim a further step in the method of claim 1, or how this step fits into the method of claim 1. It is further not clear what the DNA is isolated from, as the method of claim 1 requires a step of providing what appears to be already isolated DNA.

Applicant's claim 35 is directed to the method of claim 31, further comprising storing the DNA at a temperature between about –7°C to about 24°C. It is not clear if only the DNA is stored at a low temperature, or if the entire 'holding member' is stored at the specified temperature.

Applicant's claim 38 is directed to the method of claim 16, further comprising disposing on the box a computer readable medium embodying personal information of the subject whose DNA is stored in the hermetically sealed containers. There is insufficient antecedent basis in claim 16; it appears the method was intended to be dependent on claim 31, not claim 16, examination has been conducted as such.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-15 and 31-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ando et al (J. Pharm. Sci, 1999), in view of "Kevin Duerinck Genealogy Page" (March 2001) and CATGee, Ltd (Product and Company Info, available before Jan. 2004), and further in view of Cadet et al (Biol. Chem, 1997), Kiefer (US Patent 3,907,586), Labconco ("A Guide to Freeze Drying for the Laboratory," ©1997, available Jan. 1988), Bowman et al (WO 03/031935), and Gilbert et al (Current Protocols in Human Genetics, 1998).

Applicant's claim 1 is directed to a method for long-term storage of hereditary information, comprising providing a genetic sample comprising lyophilized DNA and sugar in a hermetically sealed UV blocking container under an inert gas, wherein the DNA is substantially free of magnesium. Claim 2 requires the sugar to be a monosaccharide or a disaccharide. Claim 3 requires the sugar to be a disaccharide. Claim 4 requires the disaccharide to be sucrose or trehalose. Claim 5 requires the inert gas to be nitrogen or argon. Claim 6 requires the UV blocking container to comprise borosilicate. Claims 7-9 require specific amounts of DNA to be included in the sample. Claim 10 requires the DNA to be lyophilized. Claim 11 requires the DNA to be obtained from the blood of a subject. Claim 12 requires the sample to be stored at a temperature between about $-7^{\circ}C$ to about $24^{\circ}C$. Claim 13 requires the sample to further comprise TRIS or EDTA. Claim 14 requires the DNA to be genomic DNA. Claim 15 requires a further step of isolating the DNA.

Applicant's claim 31 is directed to a method for long-term storage of hereditary information, comprising providing a genetic sample comprising lyophilized DNA and sugar in a hermetically sealed UV blocking container under an inert gas, and placing the sealed UV blocking container into a holding member that is inserted into an aperture of a box that together forms a kit for the long-term storage of hereditary information, wherein the DNA is substantially free of magnesium. Claim 32 requires the sugar to be a monosaccharide or a disaccharide. Claim 33 requires the inert gas to be nitrogen or argon. Claim 34 requires sample to comprise greater than 20 ug of DNA. Claim 35 requires the sample to be stored at a

temperature between about –7°C to about 24°C. Claim 36 requires the DNA to be genomic DNA. Claim 37 requires the holder member to hold four hermetically sealed containers of the lyophilized DNA and sugar. Claim 38 requires a further step of disposing on the box a computer readable medium embodying personal information of the subject whose DNA is stored in the hermetically sealed containers. Claim 39 requires the box to be made of cardboard. Claim 40 requires the holder member to be made of a transparent plastic.

Ando et al teach a method for providing a genetic sample comprising lyophilized DNA samples that are stable for storage at room temperature (about 25°C, which applicant calls storage at a temperature between about considered to be about –7°C to about 24°C) (See Ando et al, Pg. 127, col. 1). Ando et al do not teach inclusion of magnesium ions or any component that comprise magnesium; therefore the DNA appears to be substantially free of magnesium. Ando et al also teach that by including sugars, such as disaccharides trehalose and sucrose, and the monosaccharide glucose, in the DNA solution, the stability of the lyophilized DNA product is increased (See Ando et al, Pg. 128, col. 1-2 and Table 3 and Figure 2). Ando et al also teach that EDTA in the DNA sample increases stability (See Ando et al, Pg. 127, col. 2- Pg. 128, col. 1). Therefore Ando et al teach a method of providing a genetic sample comprising lyophilized DNA, sugar (including trehalose, sucrose, or glucose), and EDTA (Claims 2-4, 10, 12, 13, 15, and 32).

Ando et al use 20 ug samples of DNA (See Ando et al, Pg. 127, col. 1); however, it would have been obvious to one of ordinary skill in the art to lyophilize any desired quantity of DNA based on the sample quantity provided or on the needs of the experiments to be carried out. One of ordinary skill in the art would have a reasonable expectation of successfully scaling up the procedure to perform the lyophilization process on any amount of DNA sample provided. It is well established principle in patent law that the mere scaling up of a prior art process capable of being scaled up, does not establish patentability in a claim to an old process or product capable of being scaled up, See *In re Rinehart,* 531

F.2d 1048, 189 USPQ 143 (CCPA 1976). In general, differences in size or proportion do not distinguish the claimed invention from prior art that discloses the same product in a different size or proportion, especially when the difference in size or proportion has no effect on the function of the product (Claims 7-9 and 34).

Though Ando et al teach methods of providing lyophilized DNA and sugar and/or EDTA, wherein the DNA is substantially free of magnesium, they do not teach providing the lyophilized genetic sample in a hermetically sealed UV blocking container under an inert gas. However, at the time the invention was made it would have been well within the purview of one of ordinary skill in the art to provide the genetic sample in a hermetically sealed UV blocking container under an inert gas in order to preserve the genetic sample for long-term storage. One of ordinary skill in the art would have been motivated to preserve the genetic sample for long-term storage because personal long-term storage of ones' own DNA has become increasingly popular for security reasons and for family genealogy research. For example, Duerinck suggests archiving ones' family's DNA for future genetic testing, in case a medical problem arises one day, or for genealogical purposes, such as finding relatives. Other companies provide DNA storage services, such as CATGee Ltd, who suggest saving DNA for protection of ones' identity, or as a unique gift (The DNA storage services provided by CATGee Ltd were available before Jan 2004, as evidenced by the article in "UK Trade & Investment" dated 21 April 2003). Therefore, one of ordinary skill in the art would have been motivated to lyophilize their genetic samples, in the method of Ando et al, in order to allow for long-term storage of the genetic sample. Additionally, in order to protect the lyophilized genetic sample from degradation or deterioration during storage, it would have been well within the purview of one of ordinary skill in the art, at the time the invention was made, to store the lyophilized sample in a UV blocking container under an inert gas. One of ordinary skill in the art would have been motivated to store the DNA sample in a UV blocking container because UV rays damage DNA (See Cadet et al, abstract & Fig. 1); therefore it would have been obvious to one of ordinary

skill in the art to store the genetic sample in a container that blocks UV rays, such as the UV blocking borosilicate and tin vials of Kiefer (See Kiefer, abstract & col. 3, ln 63-col. 4, ln 9). One would expect the vials of Kiefer to protect the genetic sample from UV damage because Kiefer teaches the vials effectively protect the contained sample from UV damage (See Kiefer col. 3, ln 63-col. 4, ln 9). One of ordinary skill in the art would also have been motivated to store the DNA sample in the above mentioned container under an inert gas, such as nitrogen or argon because oxygen and moisture are detrimental to DNA (See Labconco, Pg. 8); therefore it is routine practice to apply vacuum to the sample container and backfill with an inert gas such as nitrogen or argon (See Labconco, Pg. 7, col. 2). One would expect success backfilling the vials of Kiefer with nitrogen or argon gas because such process is commonly known in the art. Therefore in order to protect the genetic samples for long-term storage it would have been within the purview of one skilled in the art to hermetically seal the genetic sample in the borosilicate and tin vials of Kiefer under an inert gas, in order to protect the genetic sample from UV rays and oxygen and moisture, all of which are known to damage and deteriorate DNA (Claims 1, 5, 6, and 33).

Still further, it would have been well within the purview of one of ordinary skill in the art, at the time the invention was made, to place the genetic samples, contained in a UV blocking, hermetically sealed container under an inert gas, in a holding member that is to be placed in a box for long-term storage of the sample (Claim 31). One of ordinary skill in the art would have been motivated to place the sealed container in a holding member for placement in a box in order to not lose the small container comprising the genetic information. The company CATGee, Ltd even provides display kits that comprise holding members for display of the genetic information, which can either be placed in a safe, or displayed in the home. It would be further obvious to one of ordinary skill in the art to place four of the hermetically sealed containers in a single box, in order to store an entire family's genetic information, CATGee, Ltd provides such family DNA kits. Additionally, please note that multiplication or duplication of parts (such as multiplication of the number of holding members in the box) does not impart patentable

significance unless a new and unexpected result is produced, see *In re Harza,* 274 F.2d 660, 124 USPQ 378 (CCPA 1960) (Claim 37). It would further be obvious to one of ordinary skill in the art to use any suitable material for the box and holder member of the kit; therefore it would have been obvious to one of ordinary skill in the art to use cardboard box and transparent plastic as the holding members (Claims 39 and 40). One of ordinary skill in the art would have been motivated to use a cardboard box based on the vast availability of cardboard, its popularity as box material, and the simplicity with which it can be folded into different box shapes. One of ordinary skill in the art would have been motivated to use transparent plastic material for the holding members because of the malleability of plastic, allowing it to easily be formed to hold the containers. One would have expected success using cardboard and plastic because they are both known in the art to be suitable materials for forming storage containers.

Additionally, in order to protect ones' identity, as suggested by CATGee, Ltd, one may not wish to display their name directly on the container comprising their genetic material; therefore it would have been obvious to one of ordinary skill in the art to use a barcode (which applicant calls a computer readable format) to label the container comprising their genetic material, such as that taught by Bowman et al (See Bowman, Pg. 9, ln 16-23) (Claim 38). One of ordinary skill in the art would have been motivated to conceal their name and personal information from the label on the container in order to protect their identity, use of a bar code would allow only those with proper access to the bar code key to identify the samples. One would expect success because use of bar codes as cryptic identifiers is well known in the art (See, e.g. Bowman et al).

Finally, though Ando et al use plasmid DNA from *E.coli*, and not genomic DNA from blood, it would have been obvious to one of ordinary skill in the art to use any type of DNA, including genomic DNA from blood (Claims11, 14, and 36). One of ordinary skill in the art would have been particularly motivated to lyophilize genomic DNA from blood when preserving family DNA for future medical testing or genealogy purpose, such as described by Duerinck or by CATGee, Ltd. Duerinck and

CATGee, Ltd teach that DNA from blood is best for archiving purposes, as testing labs can run the most thorough tests on genomic blood DNA, particularly for genetic testing purposes. Obtaining genomic DNA from blood samples is routine practice, known to one of ordinary skill in the art (See Gilbert et al). One of ordinary skill in the art would have expected success lyophilizing genomic DNA from blood in the same manner as Ando et al teaches for lyophilization of plasmid DNA, because plasmid DNA and genomic DNA share the same basic structure, and one skilled in the art would recognize that lyophilization of DNA is a routine practice, and thus would expect success (Claims 11 and 14).

Therefore the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Claims 1-12, 14-15 and 31-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Volkin et al (US 2002/0156037), in view of "Kevin Duerinck Genealogy Page" (March 2001) and CATGee, Ltd (Product and Company Info, available before Jan. 2004), and further in view of Cadet et al (Biol. Chem, 1997), Kiefer (US Patent 3,907,586), Labconco ("A Guide to Freeze Drying for the Laboratory," ©1997, available Jan. 1988), Bowman et al (WO 03/031935), and Gilbert et al (Current Protocols in Human Genetics, 1998).

Applicant's claim 1 is directed to a method for long-term storage of hereditary information, comprising providing a genetic sample comprising lyophilized DNA and sugar in a hermetically sealed UV blocking container under an inert gas, wherein the DNA is substantially free of magnesium. Claim 2 requires the sugar to be a monosaccharide or a disaccharide. Claim 3 requires the sugar to be a disaccharide. Claim 4 requires the disaccharide to be sucrose or trehalose. Claim 5 requires the inert gas to be nitrogen or argon. Claim 6 requires the UV blocking container to comprise borosilicate. Claims 7-9 require specific amounts of DNA to be included in the sample. Claim 10 requires the DNA to be lyophilized. Claim 11 requires the DNA to be obtained from the blood of a subject. Claim 12 requires

the sample to be stored at a temperature between about –7°C to about 24°C. Claim 14 requires the DNA to be genomic DNA. Claim 15 requires a further step of isolating the DNA.

Applicant's claim 31 is directed to a method for long-term storage of hereditary information, comprising providing a genetic sample comprising lyophilized DNA and sugar in a hermetically sealed UV blocking container under an inert gas, and placing the sealed UV blocking container into a holding member that is inserted into an aperture of a box that together forms a kit for the long-term storage of hereditary information, wherein the DNA is substantially free of magnesium. Claim 32 requires the sugar to be a monosaccharide or a disaccharide. Claim 33 requires the inert gas to be nitrogen or argon. Claim 34 requires sample to comprise greater than 20 ug of DNA. Claim 35 requires the sample to be stored at a temperature between about –7°C to about 24°C. Claim 36 requires the DNA to be genomic DNA. Claim 37 requires the holder member to hold four hermetically sealed containers of the lyophilized DNA and sugar. Claim 38 requires a further step of disposing on the box a computer readable medium embodying personal information of the subject whose DNA is stored in the hermetically sealed containers. Claim 39 requires the box to be made of cardboard. Claim 40 requires the holder member to be made of a transparent plastic.

Volkin et al teach a method for providing a genetic sample comprising lyophilized DNA that are stable for storage over a range of temperatures including –20°C, 0°C, and 25°C (which applicant calls storage at a temperature between about considered to be about –7°C to about 24°C) (See Volkin et al, Pg. 24, paragraphs 0222-0223). Volkin et al do not teach inclusion of magnesium ions or any component that comprise magnesium; therefore the DNA appears to be substantially free of magnesium. Volkin et al also teach that by including sugars, such as amorphorous disaccharides lactose and sucrose greatly stabilized the DNA, in the DNA solution (See Volkin et al, Pg. 24, paragraph 0224). Therefore Volkin et al teach a method of providing a genetic sample comprising lyophilized DNA and sugar (including sucrose) (Claims 2-4, 10, 12, 15, and 32).

Volkin et al use 20 ug samples of DNA (See Volkin et al, Pg. 24, paragraph 0223); however, it would have been obvious to one of ordinary skill in the art to lyophilize any desired quantity of DNA based on the sample quantity provided or on the needs of the experiments to be carried out. One of ordinary skill in the art would have a reasonable expectation of successfully scaling up the procedure to perform the lyophilization process on any amount of DNA sample provided. It is well established principle in patent law that the mere scaling up of a prior art process capable of being scaled up, does not establish patentability in a claim to an old process or product capable of being scaled up, See *In re Rinehart,* 531 F.2d 1048, 189 USPQ 143 (CCPA 1976). In general, differences in size or proportion do not distinguish the claimed invention from prior art that discloses the same product in a different size or proportion, especially when the difference in size or proportion has no effect on the function of the product (Claims 7-9 and 34).

Though Volkin et al teach methods of providing lyophilized DNA and sugar, wherein the DNA is substantially free of magnesium, they do not teach providing the lyophilized genetic sample in a hermetically sealed UV blocking container under an inert gas. However, at the time the invention was made it would have been well within the purview of one of ordinary skill in the art to provide the genetic sample in a hermetically sealed UV blocking container under an inert gas in order to preserve the genetic sample for long-term storage. One of ordinary skill in the art would have been motivated to preserve the genetic sample for long-term storage because personal long-term storage of ones' own DNA has become increasingly popular for security reasons and for family genealogy research. For example, Duerinck suggests archiving ones' family's DNA for future genetic testing, in case a medical problem arises one day, or for genealogical purposes, such as finding relatives. Other companies provide DNA storage services, such as CATGee Ltd, who suggest saving DNA for protection of ones' identity, or as a unique gift (The DNA storage services provided by CATGee Ltd were available before Jan 2004, as evidenced by the article in "UK Trade & Investment" dated 21 April 2003). Therefore, one of ordinary skill in the

art would have been motivated to lyophilize their genetic samples, in the method of Volkin et al, in order to allow for long-term storage of the genetic sample. Additionally, in order to protect the lyophilized genetic sample from degradation or deterioration during storage, it would have been well within the purview of one of ordinary skill in the art, at the time the invention was made, to store the lyophilized sample in a UV blocking container under an inert gas. One of ordinary skill in the art would have been motivated to store the DNA sample in a UV blocking container because UV rays damage DNA (See Cadet et al, abstract & Fig. 1); therefore it would have been obvious to one of ordinary skill in the art to store the genetic sample in a container that blocks UV rays, such as the UV blocking borosilicate and tin vials of Kiefer (See Kiefer, abstract & col. 3, ln 63-col. 4, ln 9). One would expect the vials of Kiefer to protect the genetic sample from UV damage because Kiefer teaches the vials effectively protect the contained sample from UV damage (See Kiefer col. 3, ln 63-col. 4, ln 9). One of ordinary skill in the art would also have been motivated to store the DNA sample in the above mentioned container under an inert gas, such as nitrogen or argon because oxygen and moisture are detrimental to DNA (See Labconco, Pg. 7); therefore it is routine practice to apply vacuum to the sample container and backfill with an inert gas such as nitrogen or argon (See Labconco, Pg. 7, col. 2). One would expect success backfilling the vials of Kiefer with nitrogen or argon gas because such process is commonly known in the art. Therefore in order to protect the genetic samples for long-term storage it would have been within the purview of one skilled in the art to hermetically seal the genetic sample in the borosilicate and tin vials of Kiefer under an inert gas, in order to protect the genetic sample from UV rays and oxygen and moisture, all of which are known to damage and deteriorate DNA (Claims 1, 5, 6, and 33).

Still further, it would have been well within the purview of one of ordinary skill in the art, at the time the invention was made, to place the genetic samples, contained in a UV blocking, hermetically sealed container under an inert gas, in a holding member that is to be placed in a box for long-term storage of the sample (Claim 31). One of ordinary skill in the art would have been motivated to place the

sealed container in a holding member for placement in a box in order to not lose the small container comprising the genetic information. The company CATGee, Ltd even provides display kits that comprise holding members for display of the genetic information, which can either be placed in a safe, or displayed in the home. It would be further obvious to one of ordinary skill in the art to place four of the hermetically sealed containers in a single box, in order to store an entire family's genetic information, CATGee, Ltd provides such family DNA kits. Additionally, please note that multiplication or duplication of parts (such as multiplication of the number of holding members in the box) does not impart patentable significance unless a new and unexpected result is produced, see *In re Harza,* 274 F.2d 660, 124 USPQ 378 (CCPA 1960) (Claim 37). It would further be obvious to one of ordinary skill in the art to use any suitable material for the box and holder member of the kit; therefore it would have been obvious to one of ordinary skill in the art to use cardboard box and transparent plastic as the holding members (Claims 39 and 40). One of ordinary skill in the art would have been motivated to use a cardboard box based on the vast availability of cardboard, its popularity as box material, and the simplicity with which it can be folded into different box shapes. One of ordinary skill in the art would have been motivated to use transparent plastic material for the holding members because of the malleability of plastic, allowing it to easily be formed to hold the containers. One would have expected success using cardboard and plastic because they are both known in the art to be suitable materials for forming storage containers.

Additionally, in order to protect ones' identity, as suggested by CATGee, Ltd, one may not wish to display their name directly on the container comprising their genetic material; therefore it would have been obvious to one of ordinary skill in the art to use a barcode (which applicant calls a computer readable format) to label the container comprising their genetic material, such as that taught by Bowman et al (See Bowman, Pg. 9, ln 16-23) (Claim 38). One of ordinary skill in the art would have been motivated to conceal their name and personal information from the label on the container in order to protect their identity, use of a bar code would allow only those with proper access to the bar code key to

identify the samples. One would expect success because use of bar codes as cryptic identifiers is well known in the art (See, e.g. Bowman et al).

Finally, though Volkin et al use plasmid DNA, and not genomic DNA from blood, it would have been obvious to one of ordinary skill in the art to use any type of DNA, including genomic DNA from blood (Claims11, 14, and 36). One of ordinary skill in the art would have been particularly motivated to lyophilize genomic DNA from blood when preserving family DNA for future medical testing or genealogy purpose, such as described by Duerinck or by CATGee, Ltd. Duerinck and CATGee, Ltd teach that DNA from blood is best for archiving purposes, as testing labs can run the most thorough tests on genomic blood DNA, particularly for genetic testing purposes. Obtaining genomic DNA from blood samples is routine practice, known to one of ordinary skill in the art (See Gilbert et al). One of ordinary skill in the art would have expected success lyophilizing genomic DNA from blood in the same manner as Volkin et al teaches for lyophilization of plasmid DNA, because plasmid DNA and genomic DNA share the same basic structure, and one skilled in the art would recognize that lyophilization of DNA is a routine practice, and thus would expect success (Claims 11 and 14).

Therefore the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Allison M. Ford whose telephone number is 571-272-2936. The examiner can normally be reached on 7:30-5 M-Th, alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Allison M Ford
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LEONB. LANKFORD, JR.
PRIMARY EXAMINER